

### **REMARKS**

Claims 18-22 remain in the application. Claims 1-7, 11, and 14-17 have been canceled. Claims 19 and 21 were allowed. Claims 8-10, 12, and 13 were withdrawn from consideration.

### **Rejections under 35 U.S.C. §112, First Paragraph**

In the Office Action of May 8, 2003, claims 18 and 20 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the invention. The Examiner asserts that the applicants have set forth only the antibody produced by the cell line deposited under accession number 930720177.

Applicants respectfully traverse. The application, as filed, sets forth a detailed description of a method for preparing a monoclonal antibody. Starting on page 4, the specification provides a method for preparing a hybridoma cell line and the antibodies it produces. Specifically, the specification describes using the general method of, for example, Kohler and Milstein to produce a hybridoma cell line. A synthetic peptide of suitable residues is conjugated to BSA and used to immunize mice. The monoclonal antibodies produced are screened and confirmed to bind to rat and mammalian AT<sub>1</sub> receptors. Based on the specification, one skilled in the art would be able to form an antibody of the type claimed without resort to undue experimentation. Having established that a synthetic peptide of a specific peptide sequence of importance to the detection of AT<sub>1</sub> receptors (SEQ. ID No. 1) can be used to produce a cell line, the procedures outlined in the specification for forming a monoclonal antibody could be readily reproduced in mouse or other convenient animal species by one skilled in the art. There is no requirement that the specification describe all antibodies, as the Examiner suggests. The specification also describes how to form a kit by tagging the monoclonal antibody with a compound that fluoresces at various wavelengths (Page 4, last paragraph). One skilled in the art would be able to form such a kit without undue experimentation. Accordingly, it is respectfully requested that the rejection be withdrawn.

**Rejections under 35 U.S.C. §102(b)**

Claims 18 and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Reilly, EP 0 273 453. Reilly discloses a monoclonal antibody for Angiotensin II. In the present application, a monoclonal antibody capable of binding to the AT<sub>1</sub> sub-type of the Angiotensin II **receptor** is disclosed. Antibodies which bind to a hormone and antibodies which bind to a receptor of a hormone are clearly distinct species. Reilly's antibody is designed to block the biological activity of Angiotensin II, not its receptor.

**Claim 18** has been amended to emphasize this distinction. Claim 18 now recites a diagnostic test kit comprising a monoclonal antibody attached to a detectable label, wherein said monoclonal antibody is capable of binding to the mammalian AT<sub>1</sub> subtype of the angiotensin II receptor and binds specifically to a peptide having the amino acid sequence (SEQ ID. No. 1) Glu--Asp--Gly--Ile--Lys--Arg--Ile--Gln--Asp--Asp.

Reilly makes no suggestion of forming an antibody capable of binding to mammalian AT<sub>1</sub> subtype of the angiotensin II **receptor** or of binding to the amino acid sequence SEQ ID. No. 1. Nor is there any suggestion in Reilly of why this would be beneficial. The present applicants have found that the present kit has a variety of applications, including the detection of breast cancer (page 5).

Accordingly, it is submitted that claim 18, and claim 20 dependent therefrom, distinguish patentably and unobviously over the reference of record.

New **claim 22** is similar to claim 18, but recites a diagnostic test kit comprising a monoclonal antibody attached to a detectable label. The monoclonal antibody binds specifically to a peptide having the amino acid sequence (SEQ ID. No. 1) Glu--Asp--Gly--Ile--Lys--Arg--Ile--Gln--Asp--Asp found in the mammalian AT<sub>1</sub> subtype of the angiotensin II receptor. Reilly makes no suggestion of forming a diagnostic test kit which binds to an amino acid sequence found in the mammalian AT<sub>1</sub> subtype of the angiotensin II receptor.


Accordingly, it is submitted that claim 22 distinguishes patentably and unobviously over the reference of record.

**CONCLUSION**

The above response and amendment are considered to place the application in condition for allowance. A prompt and favorable examination is respectfully requested.

Respectfully submitted,

**FAY, SHARPE, FAGAN,  
MINNICH & McKEE, LLP**

A handwritten signature in cursive script, appearing to read "Jay F. Moldovanyi", is written over a horizontal line.

Jay F. Moldovanyi, Reg. No. 29,678  
Ann M. Skerry, Reg. No. 45,655  
1100 Superior Avenue, 7th Floor  
Cleveland, Ohio 44114-2518  
216/861-5582